



**KMCT**

**COLLEGE OF ALLIED HEALTH SCIENCES**

Affiliated to Kerala University of Health Sciences and approved by Govt.of Kerala

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# **KMCT COLLEGE OF ALLIED HEALTH SCIENCES**



## **CODE OF ETHICS**





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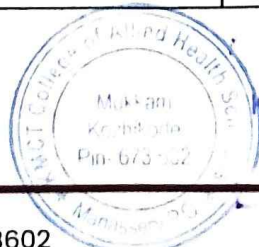
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## THE OBJECTIVE

Establishing a thorough and clear set of rules and guidelines that direct researchers' ethical behaviour at every stage of the study process is the aim of an institutional research review code of ethics. The Code of Ethics for Institutional Research Review Committee aims to create moral guidelines and norms that will guide the work of institutional researchers. All researchers must abide by the relevant legal, ethical, and professional frameworks, as stated in the KMCT CAHS code of conduct and ethics.

These guidelines serve several essential purposes:

### 1. Securing the participants:

Ensuring the safety and welfare of study participants is one of the main goals of an institutional research review code of ethics, especially when the research involves human subjects. The code

describes how to get informed permission, reduce any risks, keep information private, and deal with any negative outcomes that might occur throughout the study. Researchers can guarantee that participants are treated with dignity and respect by following ethical rules.

### 2. Maintaining the Integrity of Research:

Ethical standards encourage honesty and integrity in research. They ensure that study findings are truthful and credible by regulating actions like data fabrication, falsification, and plagiarism. Maintaining integrity is essential to fostering confidence both among the general public and the scientific community.

### 3. Ensuring Validity and Credibility:

Researchers can improve their research's validity and reliability by adhering to ethical principles. The robustness of study conclusions is enhanced by transparent reporting, impartial methodology, and ethical data gathering. These factors also facilitate the replication and verification of the findings by other researchers.



#### **4. Preventing Harm and Misuse:**

Potential harm to participants, the research community, and society at large can be avoided with the support of a clear and comprehensive code of ethics in research. It encourages ethical and socially beneficial research and discourages the use of research for negative or exploitative ends.

#### **5. Compliance with Regulations:**

Institutional and regulatory rules controlling research are frequently in line with ethical norms. Researchers can protect themselves and their organizations from potential legal and ethical effects by following these recommendations, which guarantee conformity with laws and policies.

#### **6. Responsibly Conduct Research:**

A research culture that prioritizes honesty, openness, and responsibility is fostered by a Code of Ethics, which lays out explicit guidelines for responsible research conduct. This fosters an atmosphere that motivates academics to carry out their work in a moral and responsible manner.

#### **7. Public Trust and Confidence:**

Building and preserving public trust and confidence in the scientific community depends on ethical research practices. The public is more inclined to believe research findings and the wider effects of scientific discoveries when it is conducted ethically.

#### **8. International Collaboration:**

Ethical principles frequently apply internationally and promote cooperation amongst academics from various nations and cultural backgrounds. Globally oriented research is encouraged and knowledge exchanged when there is a common ethical foundation.



### **9. Advice on Ethical Dilemma:**

Research frequently poses difficult questions about ethics. Having a code of ethics gives researchers direction on how to address and overcome these difficulties in a way that is morally right.

### **10.Ethical Responsibility as Researchers:**

A code of ethics in research should ultimately serve to remind researchers of their moral obligations to society, study subjects, and the integrity of science. It reaffirms the dedication to carrying out morally and ethically sound research that advances humankind.



## PRINCIPLES OF CODE OF ETHICS

A code of ethics is a set of rules or norms that control how people behave inside a specific community, organization, or profession. A code of ethics' guiding principles usually set forth the essential ideals and norms that participants in the group are expected to uphold. These universal principles can be found in many codes of ethics, while specific codes may differ depending on the situation.

**Integrity:** Maintaining sincerity, veracity, and openness in all dealings, both personal and professional. avoiding conflicts of interest and conducting oneself in a way that encourages confidence and trust.

**Respect:** Showing consideration, justice, and decency to every person, regardless of their origins, social standing, or religious convictions.

**Confidentiality:** Maintaining the privacy of persons and stakeholders while protecting sensitive information, unless there's a compelling cause to reveal it, is known as confidentiality.

**Responsibility:** Being responsible is accepting accountability for one's choices and actions, realising their effects, and facing the repercussions—both negative and positive.

**Professional Competence:** Making an effort to uphold and improve one's professional knowledge, abilities, and skills in order to deliver the best possible work or services.

**Impartiality and Objectivity:** Being impartial and objective means avoiding bias or partiality in favour of unbiased analysis and facts while making judgments and offering advice.





**Lawfulness and Compliance:** Following all relevant laws, rules, and guidelines that control the industry or group.

**Social Responsibility:** Having an understanding of how one's actions impact society and the environment more broadly, and making an effort to contribute to community improvement.

**Avoiding Harm:** Taking steps to shield people, organizations, or the general public from harm or unfavourable outcomes.

**Constant Improvement:** Making a commitment to evaluate oneself and look for chances to develop personally and make better moral decisions.

**Conflict Resolution:** Resolving ethical issues and disputes in a positive, transparent manner, asking for help when needed.

**Professionalism:** Upholding a high standard of behaviour, speech, and appearance in order to project professionalism.

These values support professionals and organizations in making moral decisions and cultivating a climate of accountability, respect, and trust. It's crucial to remember that any industry or group may have a special code of ethics suited to their own requirements and difficulties.



## RESPONSIBLE CONDUCT OF RESEARCH

All researchers must obtain approval from the Institutional Research Review Committee (IRRC) and Institutional Scientific Review Committee (ISRC) before starting any research in compliance with the guidelines. Clinical Trial Registry-India (CTRI) registration is mandatory for clinical trials.

The term "Responsible Conduct of Research" (RCR) describes the moral precepts and directives that scientists should follow when carrying out their investigations and managing the findings. It includes a collection of principles, industry norms, and best practices designed to uphold honesty, openness, and responsibility in the research process. RCR is necessary to uphold the validity and reliability of research findings as well as the public's confidence in the scientific community.

The key elements of conducting research responsibly include:

**Honesty:** When collecting, analyzing, and reporting data, researchers should always act with accuracy and sincerity. Plagiarism, fabrication, or fabrication are grave violations of research ethics.

**Integrity:** High moral and ethical standards must be followed by researchers. To do this, one must be impartial and fair, abstain from conflicts of interest, and declare any potential conflicts that might have an impact on the research.

**Transparency:** To enable replication and validation by other researchers, researchers must give enough information about their procedures and findings. It is encouraged to share data and methods in an open manner.

**Objectivity:** Research should be conducted in an unbiased manner. Scholars should strive to base their conclusions solely on the available evidence, refraining from modifying data or findings to suit their own purposes





**Respect for Participants:** When using human subjects in research, scientists should have their informed consent, maintain participant confidentiality and privacy, and reduce any risks or harm to them.

**Animal Welfare:** To guarantee that animals are treated humanely and to reduce any suffering or discomfort, researchers doing studies on animals should abide by ethical rules.

**Appropriate Mentoring:** It is the duty of senior researchers to supervise and advise junior researchers, making sure that the latter are aware of and adhere to ethical research procedures.

**Publication Ethics:** Writers should correctly and truthfully submit their work, giving due credit to others who have contributed. It is best to prevent plagiarism, including self-plagiarism, and to correctly credit all of your sources.

**Data management:** When it's suitable, researchers should make their study data available to other academics by keeping precise and well-organized records of it.

**Peer Review:** To enhance the quality of scientific papers, researchers should participate in the peer review process with honesty, decency, and a commitment to confidentiality. Additionally, they should provide objective and constructive criticism

**Conflict of Interest:** It is important to report any potential conflicts of interest, including any financial, personal, or institutional ties that might have an impact on the research.



## ETHICAL CONSIDERATIONS IN COLLABORATIVE RESEARCH

In order to guarantee that research is carried out responsibly and that it respects the rights, dignity, and well-being of all parties involved, ethical considerations in collaborative research are crucial. When several scholars or research institutes collaborate on a project, they are working towards a common goal. In addition to preserving scientific integrity and fostering confidence amongst partners, ethical norms also serve to protect the rights of participants. Important ethical factors for joint research include the following:

### **Informed Consent:**

Acquiring informed consent from every individual involved is an essential ethical obligation. Participants' rights, any risks and rewards, the goals of the research, and their voluntary participation must all be clearly disclosed to them, according to collaborators. Sometimes it takes more work to make sure informed consent is really understood because of linguistic or cultural difficulties.

**Data privacy and confidentiality:** Partners need to set up safeguards to preserve participant data privacy. This involves adhering to institutional norms and data protection laws, storing data securely, and anonymizing data when appropriate.

**Research Approval and Compliance:** Collaborators must secure from pertinent institutional research review boards (IRBs) or ethics committees the necessary research approvals. In order to guarantee uniformity and conformity, each cooperating institution should adhere to its own research methods and criteria while working with others.



**Equity and Inclusion:** In order to ensure representation from a variety of demographics, collaborative research should work to be inclusive and equitable in participant selection. It's critical to avoid discriminatory hiring practices and to identify power disparities among partners.

**Authorship and publishing:** To properly recognise and represent the contributions of each collaborator, precise rules pertaining to authorship and publishing credit should be developed. Authorship disputes ought to be settled in an open and moral manner.

**Conflict of Interest:** Any potential conflicts of interest that might affect the research or its conclusions must be declared by all contributors. Research integrity is preserved by financial and personal interest transparency.

**Collaboration and Communication:** To make sure that everyone is on the same page and that ethical issues are properly addressed, open and efficient communication amongst collaborators is crucial. Roles and responsibilities that are well-defined can reduce the likelihood of misunderstandings.

**Community Engagement:** It's critical to involve stakeholders in research involving communities from the outset. Engaging the community can guarantee that research is valuable, pertinent, and sensitive to cultural differences.

**Responsible Data Sharing:** Information must be shared responsibly, taking into account privacy and confidentiality issues, and according to data use agreements when it is shared with partners or made publicly accessible.



## VULNERABLE POPULATION IN RESEARCH

A vulnerable population in research is a group of people who might be more likely to suffer harm or who might have less autonomy, which could leave them open to being taken advantage of or coerced. When participating in research projects, these populations need to be given extra respect and protection to defend their rights and to ensure their safety and well being. Regulations and ethical norms are in place to protect the interests of vulnerable people.

Some examples of vulnerable populations in research include:

**Children:** Due to their restricted capacity for giving informed consent, minors who are not yet of legal consent-giving age are regarded as vulnerable. Informed agreement from parents or legal guardians is required, and researchers must make sure the study is in the best interests of the children.

**Pregnant Women:** Due to possible dangers to the mother and the unborn child, pregnant women may be particularly vulnerable. Before using them in studies, researchers must carefully weigh the benefits and risks.

**Older persons:** Due to cognitive decline, it may be difficult for older persons to give informed permission or comprehend study methods in their entirety.

**People with Cognitive Impairment:** People who suffer from dementia or intellectual disability, for example, could find it difficult to comprehend the consequences of participating in research, therefore extra precautions are necessary.

**People with Serious Medical Conditions:** People who have serious or life-threatening illnesses should not be excessively burdened by involvement, as their health situation may make them vulnerable. Populations that are socioeconomically disadvantaged may be more susceptible to exploitation or have less access to resources, which may influence their willingness to participate in research.



**Prisoners:** Research with incarcerated individuals must be carefully examined ethically because they may have limited autonomy and may be forced to participate.

Researchers are required to adhere to stringent ethical rules while working with vulnerable populations. These guidelines include gaining informed consent, minimizing risks, and guaranteeing confidentiality and anonymity. When evaluating research proposals involving vulnerable populations, the Institutional Research Review Committee is essential in ensuring that ethical standards and regulatory criteria are met.



## CONFLICT OF INTEREST

In research, a conflict of interest (COI) arises when a researcher's financial or personal interests may jeopardize the objectivity, integrity, or legitimacy of their conclusions or findings. When researchers have conflicting interests that might improperly affect their conduct or decision-making while conducting study, these conflicts may occur.

COIs can appear in a number of ways, such as but not restricted to:

**Financial conflicts:** When researchers stand to gain financially from the results of their work through stock ownership, consulting fees, patents, or support from a specific business or group.

**Personal conflicts:** Researchers may be personally connected to people or organizations that the results of their research may have an impact on.

**Academic conflicts:** These conflicts can result from rivalry for resources, recognition, or advancement within the field, which may persuade scholars to accept particular findings or interpretations.

**Intellectual conflicts:** Researchers' approaches to the research or their interpretations of the findings may be skewed when they have an emotional or intellectual commitment to a certain theory or hypothesis.

Independent reviewers or committees may also be appointed by journals and funding agencies to evaluate stated conflicts of interest and determine if they constitute a substantial risk to the integrity of the study. To manage the detected conflicts, certain actions may be taken, like changing study protocols, removing oneself from decision-making, or increasing transparency.





### **PUBLIC HEALTH RESEARCH & SOCIAL AND BEHAVIOURAL SCIENCES RESEARCH FOR HEALTH**

Along with individuals, communities, populations, and the environment may all be impacted by public health research in both positive and negative ways.

In social and behavioral sciences, social justice and intersectionality need to be upheld. The concept of ethical relativism is pertinent when discussing the moral diversity found in various cultures and societies.

Numerous research projects, such as programme evaluations, demographic monitoring, registries, implementation studies, demonstration projects, community trials, surveys, etc., will be reviewed by the evaluation committees (ECs).

Based on a particular study, the EC will consider appropriate consent processes, such as oral or verbal consent, broad consent, group consent, waiver of consent, and re-consent.

Research design and implementation should take extra care if it is thought that the study may be used to abuse individuals from low-income backgrounds.

### **THE INTELLECTUAL PROPERTY RIGHT**

Granting credit where credit is due for the development of novel ideas will protect the intellectual property rights of all participating researchers. If the investigators and their institutions choose to collaborate with a sponsoring agency or business, this decision must be made at the beginning of the research project.



## TRAINING FOR MEMBERS OF THE INSTITUTIONAL RESEARCH REVIEW COMMITTEE (IRRC)

Members of the Institutional Research Review Committee (IRRC) must get training in order to guarantee that they possess the information and abilities needed to carry out their duties and obligations in an efficient manner. Reviewing and approving study proposals involving human subjects is the responsibility of ethical committees in order to protect their welfare, safety, and rights.

The following are important actions and things to think about while educating members of ethical committees:

**Fundamental Ethical Guidelines:** To begin, provide participants a summary of the core ethical precepts—autonomy, beneficence, non-maleficence, and justice—that govern research involving human subjects. Ensure that they comprehend the significance of adhering to these rules throughout the evaluation procedure.

**Relevant Local, National, and International Regulations and norms:** Educate committee members on pertinent rules and norms pertaining to research ethics. This contains papers such as the Belmont Report, the Declaration of Helsinki, and other principles unique to a particular region.

**Establishment Policies:** Make sure committee members understand the particular policies and processes for reviewing research involving human beings at their institution. These could include policies for data management, confidentiality, informed consent, and disclosing unfavourable events.



**Case Studies and settings:** Use case-based learning to have participants examine and talk about fictitious research settings that provide moral conundrums. With ethical review, this method aids in the development of their critical thinking and decision-making abilities. Members should be fully instructed on the significance of informed consent as well as the components of a permission form. Talk about the difficulties of obtaining voluntary permission and working with disadvantaged populations.

**Entanglement of Interests:** Members should get training on how to identify and handle any conflicts of interest that might develop throughout the review process. Stress the value of objectivity and fairness.

**Diversity and Cultural Sensitivity:** Make committee members aware of the value of cultural diversity, as well as how it may affect research participation and ethical issues. Talk about the ways that cultural influences might affect the planning and execution of research.

**Continuing Education:** Promote committee members' continued professional growth and education. It is imperative for members to remain informed on the most recent advancements in research ethics, as norms and regulations pertaining to the field can change over time.

**Exam Simulator Sessions:** Set up simulated review sessions so that participants can have experience assessing research proposals together. This practice can assist in determining which regions would benefit from further instruction

**Evaluation and input:** Regularly ask committee members for their opinions in order to gauge how well the training course is working. As needed, incorporate these suggestions to update and enhance the training.



**Networking and Cooperation:** Motivate committee members to work together and establish connections with researchers, pertinent stakeholders, and other ethics committees. Their comprehension of ethical review procedures can be improved by exchanging best practices and experiences.